Efficacy of CryoBalloon Focal Ablation System on Human Esophageal Barrett*s Epithelium

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This study will evaluate the efficacy of the CbFAS with the optimal safe dose on the conversion of Barrett's epithelium to healthy squamous cell epithelium in a larger cohort. Furthermore, the device performance of the improved CbFAS will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41706

Source
ToetsingOnline

Brief title
Efficacy EBCA focal

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophageal cancer, esophageal neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: C2Therapeutics
Source(s) of monetary or material Support: C2 Therapeutcs;Inc

Intervention

Keyword: Barrett's esophagus, Cryoablation, Cryotherapy, Esophageal neoplasms

Outcome measures

Primary outcome

1) Efficacy of the CbFAS, defined as the percentage of the (group of) islands

with full conversion from Barrett's epithelium to squamous cell epithelium.

Secondary outcome

1) Percentage of the (group of) islands with 50% conversion from Barrett's

epithelium to squamous cell epithelium.

2) Device performance of theimproved Cryoballoon Focal Ablation System

3) Occurrence of any adverse events.

Study description

Background summary

Barrett's Esophagus (BE) is a premalignant lesion which can lead to esophageal adenocarcinoma. This particular cancer is one of the most rapidly increasing and deadliest cancers in the western world. Patients with BE are up to 40 times more at risk of adenocarcinoma than individuals without BE. Once diagnosed with BE, a patient enters a life-long surveillance program in which upper endoscopy with biopsy are performed to survey the progression of the Barrett's tissue to cancer. For more than 20 years, many technologies have been evaluated for ablation of BE. Elimination of BE and restoration of squamous esophageal lining has been demonstrated through ablation; however, no ablation technology currently provides the necessary attributes for wide-spread adoption. The CryoBalloon Ablation System (System) is designed to address many of the limitations of ablation technologies. The simplicity of the System allows for many potential benefits to the patient, the physician, and hospital. Some of the benefits may include a shorter and safer procedure, an easier deployment minimizing the need for anesthesiology, and smaller inventory requirements and no capital equipment improving capital resource utilization The System has undergone acute and chronic animal testing. The testing was conducted to study the safety, deliverability and performance characteristics of the System. The

studies were conducted for the evaluation of the device in a normal pig esophagus at dimensions very similar to a human esophagus. General follow-up time frames were either 4 days or 28 days. Hereafter, a human trial has been performed with the circumferential balloon-cryoablation system. This too appeared safe and feasible in the treatment of a human esophagus. In the past year a study with the Cryoballoon Focal Ablation System was performed, which evaluated the safety of the CbFAS with several doses, and the device perfomance status. Safe ablations could be performed with the maximal dose (10 sec). Yet the device performance was not optimal. Recently, an improved version of the CbFAS has been developed.

Study objective

This study will evaluate the efficacy of the CbFAS with the optimal safe dose on the conversion of Barrett's epithelium to healthy squamous cell epithelium in a larger cohort. Furthermore, the device performance of the improved CbFAS will be assessed.

Study design

Prospective, multi-center, single-arm and non-randomized.

Intervention

Endoscopic balloon based cryoablation. The System has two main components: the delivery catheter with balloon probe and a disposable handle containing the cryogenic fluid. Deployed through the working channel of an endoscope, the operation of the System is very similar to the deployment of dilatation balloons. Once deployed, the balloon is simultaneously inflated and cooled with cryogenic fluid delivered from the handle. In the focal ablation balloon the cryogenic fluid will only cool a focal area from one hole in the shaft. BE cells are ablated as the balloon comes into contact with the esophagus for 10 seconds. After ablation, the System is repositioned for additional ablation or withdrawn.

Study burden and risks

Patients will undergo 2 gastroscopies in this study, which will both be performed for regular medical reasons anyway. The difference compared to regular treatment is that during the first endoscopy patients will be treated with the focal cryoablation system instead of regular focal RFA treatment. During follow-up endoscopy a biopsy will be taken from the ablated zone and a thorough inspection of the esophagus will be performed, after which the regular treatment will be performed as scheduled for regular medical reasons. This extra biopsy and inspection will prolong the enoscopy by 5 -10 minutes. Patients need to adhere to a soft diet during 2 days after the cryoablation

(unless the esophagectomy will follow directly upon the endoscopic treatment). Furthermore patients will be contacted by telephone 2 days after the cryoablation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

a) Patients with known Barrett*s esophagus, scheduled for treatment with focal radiofrequency ablation (HALO-90) [i.e. in patients with islands or residual Barrett*s after circumferential radiofrequency ablation (HALO-360) or in patients for whom circumferential radiofrequency ablation is not feasible], during which the cryoablation may be performed.
b) Patient is 18 to 80 years of age at the time of consent (inclusive).
c) Patient has provided written Informed Consent (IC) using an Informed Consent Form (ICF) that has been approved by the Institution*s reviewing IRB/EC.

d) Patient is willing and able to comply with all Clinical Investigation Plan (CIP) requirements.
e) Patient is deemed operable per standard institutional criteria.
f) Each patient will have one (group of) island of BE *1 cm2 where the Cryoballoon Focal Ablation System can be successfully positioned within the BE lesion.
g) BE lesion within the treatment zone should be flat.

Exclusion criteria

a) Esophageal stenosis preventing advancement of a therapeutic endoscope and/or within 4 cm of treatment zone.
b) Patient has a known history of unresolved drug or alcohol dependency that would limit ability to comprehend or follow instructions related to informed consent, post treatment instructions or follow-up guidelines.
c) Patient refuses or is unable to provide written informed consent.
d) Patients that are pregnant.
e) Patient with endoscopically active inflammation in the treatment zone.
f) Endoscopically visible abnormalities such as masses or nodules requiring endoscopic resection.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	C2 Therapeutics CryoBalloon Focal Ablation System (System)

Registration:	No

Ethics review

Approved WMO Date:	07-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Not approved Date:	01-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47404.018.13